GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:1695
ANSWERED ON:28.11.2007
FIXED DOSE COMBINATIONS
Hasan Chaudhary Munawwar;Jagannath Dr. M.

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Drugs Controller General of India (DCGI) has conducted a meeting at Mohali to discuss the issue of Fixed Dose Combinations (FDCs);

(b) if so, the outcome thereof alongwith name of the Participants;

(c) the follow-up action taken or being taken by the Government to weed out FDCs on the basis of the decisions taken in the said meeting;

(d) the names of the FDCs alongwith their compositions and the name of Companies who are engaged in the marketing of these drugs; and

(e) the details of the combination drugs which are likely to be banned for lack of therapeutic efficacy and withdrawn from the market?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAMADOSS)

(a) Yes Sir.

(b) & (c) The Drugs Consultative Committee meeting was attended by State Drugs Controllers at Mohali and an interaction with major Pharma Industry associations was also held.

The consensus decision taken at Mohali for withdrawal of the manufacturing licenses granted to the manufacturers for the unapproved Fixed Dose Combinations (FDCs) and also to withdraw these from the market was communicated to all State Drugs Controllers.

(d) & (e) List of unapproved 294 FDCs which was circulated to all State Drugs Controllers is enclosed at Annexure. States have been directed to withdraw these 294 FDCs as rationality, safety, and efficacy has not been established by the manufacturers as per the provisions of Drugs and Cosmetics Act and Rules thereunder. On receipt of application for such FDCs, they will be examined for their rationality, safety, and efficacy and then only marketing authorization can be considered.